under this interim final rule are eligible for an SBA guarantee to the same extent as PPP loans based on existing PPP rules.

Compliance With Executive Orders 12866, 12988, 13132, 13563, and 13771, the Paperwork Reduction Act (44 U.S.C. Ch. 35), and the Administrative Procedure Act (5 U.S.C. 553)

Executive Orders 12866, 13563, and 13771

The Office of Management and Budget has determined that this interim final rule is economically significant for the purposes of Executive Orders 12866 and 13563, and is considered a major rule under the Congressional Review Act. Treasury, however, is proceeding under the emergency provision at Executive Order 12866 Section 6(a)(3)(D) based on the need to move expeditiously to mitigate the current economic conditions arising from the COVID–19 emergency. This rule's designation under Executive Order 13771 will be informed by public comment.

Executive Order 12988

Treasury has drafted this rule, to the extent practicable, in accordance with the standards set forth in section 3(a) and 3(b)(2) of Executive Order 12988, to minimize litigation, eliminate ambiguity, and reduce burden. The rule has no preemptive or retroactive effect.

Executive Order 13132

Treasury has determined that this rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various layers of government. Therefore, Treasury has determined that this rule has no federalism implications warranting preparation of a federalism assessment.

Paperwork Reduction Act, 44 U.S.C. Chapter 35

Treasury has determined that this rule will not impose new or modify existing recordkeeping or reporting requirements under the Paperwork Reduction Act.

Inapplicability of Notice and Delayed Effective Date

The Administrative Procedure Act (APA) requirements in 5 U.S.C. 553 govern agency rulemaking procedures. Section 553(b) of the APA generally requires notice and public comment before issuance of a final rule. In addition, section 553(d) of the APA requires that a final rule have a 30-day delayed effective date. The APA, however, provides exceptions from the prior notice and public comment requirement and the delayed effective date requirements, when an agency for good cause finds that such procedures are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 553(b)(B), (d)(3). Treasury finds that prior notice and comment are impracticable and contrary to the public interest and that good cause exists to issue this interim final rule immediately.

The ongoing unprecedented situation related to COVID–19 is having a nationwide impact, as demonstrated by the declaration of a national emergency by the President. *See* Proclamation 9994 of March 13, 2020, 85 FR 15337 (Mar. 18, 2020). The interim final rule supports seasonal employers affected by COVID–19 in obtaining PPP loans to maintain their businesses and keep people employed. To protect our public interests during the ongoing national emergency, Treasury concludes, pursuant to 5 U.S.C. 553(b)(B), that there is good cause to dispense with prior public notice and the opportunity to comment on this rule before issuing this interim final rule. For the same reasons, Treasury has determined, consistent with section 553(d)(3) of the APA, that there is good cause to make this temporary final rule effective immediately.

Michael Faulkender,

Assistant Secretary for Economic Policy.

[FR Doc. 2020–09239 Filed 4–28–20; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2020–D–1304]

Temporary Policy Regarding Accredited Third-Party Certification Program Onsite Observation and Certificate Duration Requirements During the COVID–19 Public Health Emergency: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled ''Temporary Policy Regarding Accredited Third-Party Certification Program Onsite Observation and Certificate Duration Requirements During the COVID–19 Public Health Emergency.'' Given the public health emergency presented by COVID–19, this guidance document is being implemented without prior public comment because FDA has determined that prior public participation is not feasible or appropriate, but it remains subject to comment in accordance with the Agency's good guidance practices. The guidance communicates the Agency's intention not to enforce certain requirements for the onsite monitoring activities and certificates for the currently recognized accreditation bodies (ABs) and accredited third-party certification bodies (CBs) in the Accredited Third-Party Certification Program for human and animal food in certain circumstances. Because travel restrictions and advisories related to COVID–19 may impact the ability of recognized ABs and accredited CBs to conduct onsite activities, this guidance provides temporary flexibility so that recognized ABs can maintain the accreditations of their CBs, and so that already-issued certifications need not lapse, in certain circumstances.

DATES: The announcement of the guidance is published in the **Federal Register** on April 30, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–1304 for ''Temporary Policy Regarding Accredited Third-Party Certification Program Onsite Observation and Certificate Duration Requirements During the COVID–19 Public Health Emergency.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))).

Submit written requests for single copies of the guidance to the Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–607), 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Doriliz De Leon, Center for Food Safety and Applied Nutrition (HFS–607), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2772.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Temporary Policy Regarding Accredited Third-Party Certification Program Onsite Observation and Certificate Duration Requirements During the COVID–19 Public Health Emergency.'' This policy relates to the circumstances that gave rise to the public health emergency related to COVID–19 declared by the Department of Health and Human Services.

Given this public health emergency this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate. This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices. The guidance represents the current thinking of FDA on this topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

This guidance document concerns certain requirements for the recognized ABs and accredited CBs in the Accredited Third-Party Certification Program that was established in 21 CFR part 1, subpart M, as part of our implementation of the FDA Food Safety Modernization Act (Pub. L. 111–353). The Accredited Third-Party Certification Program regulation (*https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-accredited-third-party-certification*) requires recognized ABs to monitor the performance of the CB(s) they accredited. While some of the monitoring activities can be conducted remotely, some of the activities must be conducted onsite. The Accredited Third-Party Certification Program regulation also requires that accredited CBs can issue certificates for a term only up to 12 months.

Due to the impact of the travel restrictions and advisories related to COVID–19, this guidance provides flexibility to the recognized ABs and accredited CBs in the Accredited Third-Party Certification Program for certain requirements related to the onsite monitoring activities and certificates that have already been issued, in certain circumstances.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in in part 1, subpart M, have been approved under OMB control number 0910–0750.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/FoodGuidances, https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: April 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–09169 Filed 4–29–20; 8:45 am]

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